

### **Remarks**

This paper is being provided in response to the Office Action mailed July 10, 2007, for the above-referenced application. Claims 2, 4-5, 7-11, 13-20, 23-24, 34-38, 40-47, and 50-51 have been cancelled. Applicant respectfully points out that claims 60-62, 73-74, and 77-81 are also still pending in this application and were not withdrawn according to the Restriction Requirement mailed on January 10, 2007. *See* Response to Restriction Requirement, mailed on April 23, 2007. Therefore, claims 1, 3, 6, 12, 21-22, 25-33, 39, 48-49, 52-62, 73-74, and 77-81 are currently pending. Claims 1, 3, 21, 22, 25-29, 32, 48, 49, 52-56, 60, 73, 74, 77-81 have been amended. Applicant respectfully submits that the amendments to the claims do not add new subject matter.

### **Information Disclosure Statement**

Examiner has stated that the information disclosure statement (“IDS”) filed on March 13, 2004 fails to comply with 37 C.F.R. § 1.98 (a)(2) because the IDS lists references in their entirety, but only a portion of certain references were provided to the PTO. Applicant understands that only the portions of these references that have been submitted by the applicant have been considered. To the extent that additional references are material to the patentability of the pending claims and the Applicant requests any additional references be considered, Applicant will file a supplemental IDS during the prosecution of this application.

### **Drawings**

Examiner has stated that corrected drawings for Figures 2A and 2B are required in reply to the Office Action to avoid abandonment of the application. The drawings have been amended and a “New Sheet” is submitted herewith. No new matter as been entered by this amendment.

### **Specification**

Examiner has objected to the specification because the proper name “Remington” is misspelled throughout. Applicant has amended the specification to correct this formality.

Examiner has further objected to the abstract “because it is legal rather than narrative in tone and recites numerous phrases that can be implied.” Applicant has amended the abstract to correct this formality.

### **Claim Objections**

Examiner has objected to the claims because “the lines are crowded too closely together, making reading difficult.” Applicant has expanded the alignment of the claims with one and one-half line spacing.

Examiner has objected to claims 25, 26, 52, and 53 because of a misspelled word. Applicant has amended those claims to correct the misspelling.

### **Claim Rejections under 35 U.S.C. § 112**

Examiner has rejected claims 1, 3, 6, 12, 21-23, 25-33, 39, 48-50, and 52-59 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, Examiner states that claim 1 is indefinite because it “requires that the bioactive material be ‘admixed with monomers’ and yet that it be ‘shielded from the monomers by [the insoluble material]’”. The manner in which these three components are related within the composition is not clearly pointed out; for example, it is not clear whether the insoluble material coats the monomers, the bioactive material, both, or neither. It is not clear how two components can be admixed with each other and yet shielded from each other, for example.” Applicant points out that, unless defined in the specification, claim terms take on their ordinary, dictionary meaning. The term “admixed” is defined as mixed in or mixed with. Therefore, the claim element “bioactive molecules admixed with the monomers” simply means to have bioactive molecules mixed in or with monomers. The term “shielded” is defined as to protect with or as if with a shield or provide with a protective cover or shelter. Therefore, the claim element “the bioactive molecules shielded” simply means the molecules are provided with a protective cover so that they are protected from the polymerization process applied to the monomers. Applicant respectfully submits that it is clear to one of ordinary skill in the art that two components (e.g., monomers and bioactive molecules) can be admixed but that one component is shielded or

protected. In order to further prosecution and to clarify the claims with respect to other rejections, Applicant has amended claim 1.

Examiner further states that the term insoluble is a relative term, and the claim term provides no basis for comparison. Applicant has amended the claim to further clarify that which is claimed.

Examiner rejects claim 1 as being indefinite for using the term “body temperature,” which the Examiner states varies depending upon the body being measured. Applicant agrees that the term “body temperature” is defined as the internal temperature of a living organism, and that temperature would vary depending on the type and status of said living organism. However, Applicant respectfully submits that this does not make the claim indefinite. In order to further prosecution, Applicant has amended the claim to further clarify that which is claimed.

Applicant has amended claim 1 to clarify the relationship between the polymerization and the solid-gel transition. Further, claim 1 has been amended to clarify the protection of the bioactive molecules.

With respect to claim 3, Examiner states that claim 3 is indefinite for reciting the intended purpose of tissue engineering without reciting the steps of how this use is practiced. Applicant has amended claim 3 to clarify that which the Applicant claims.

Examiner states that claims 21, 25, and 27 are incomplete because they “omit essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.” Claim 21 recites the substrate system further comprising a binder. A binder is generally defined as something that produces or promotes cohesion in loosely assembled substances (e.g., components of the insoluble material). Claim 25 recites the substrate system further comprising a plasticizer. A plasticizer is generally defined as a chemical added to impart flexibility, workability, or stretchability (e.g., to the cross-linked structure). And Claim 27 recites the substrate system further comprising a disaggregant. A disaggregant is generally defined as a substance to assist in breaking another substance up or apart (e.g., to change the substrate from a solid to a gel). Applicant has amended claims 21, 25 and 27 to clarify that which Applicant claims.

Examiner requests clarification for claims 22, 23, 26 and 28 and the claimed term “or derivatives thereof.” Applicant has amended the claims to clarify that which is elected for

purposes of Examiner's search for prior art and review of the patentability of the present application.

With respect to claim 27, Examiner states that the term "disaggregant" is confusing because "claim 1 does not recite any particles that might be prevented from aggregating by the disaggregant of claim 27." As stated above, a disaggregant is generally defined as a substance to assist in breaking another substance up or apart (e.g., to change from a solid to a gel). Applicant has amended claim 27 to clarify that which is claimed.

With respect to claim 29, Examiner states that the requirement "that the bioactive molecules be "shielded by the insoluble material by granulation" ... is confusing [because] [i]t is not clear what is granulated in this claim or how such a physical form might yield protection." Applicant has amended claim 29 to clarify that which is claimed.

Examiner rejects claims 32, 48-50 and 52-56 for the same reasons set forth above regarding claims 1, 21-23, and 25-29, respectively. Applicant has amended these claims to clarify that which the Applicant claims.

Claim 32 has been further rejected because of the term "previously" in that the term "is relative, and no basis of comparison is provided in the claim." Applicant has amended this claim to clarify that which the Applicant claims.

Applicant has further amended claims 60-62, 73-74, and 77-81 in accordance with the Examiner's rejections listed above.

#### **Claim Rejections under 35 U.S.C. § 102**

Claims 1, 3, 12, 21, 25-29, 32, 39, 48, and 52-47 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,359,483 to Kaetsu et al. (hereinafter "Kaetsu") "taken in light of" U.S. Patent No. 5,047,442 to Sasaki et al. (hereinafter "Sasaki").

The present invention relates to a drug delivery or substrate system comprising photo-polymerizing monomers, bioactive molecules admixed with the monomers, wherein upon polymerization, the monomers produce a cross-linked structure that undergoes a solid-gel transition at the body temperature of the living organism to which the substrate system is administered, and further comprises a material insoluble in the monomers, wherein the insoluble material protects the bioactive molecules during the polymerization process.

Examiner states that Kaetsu teaches a composition comprising insulin ("Component A"), a bioactive protein, encapsulated in cellulose acetate ("Component B," which is insoluble in water, which is itself coated in triethyleneglycol dimethacrylate polymer ("Component C")). Examiner further states that Sasaki is cited as evidence that triethyleneglycol dimethacrylate is inherently photopolymerizable. As Examiner points out, Kaetsu discloses a bioactive molecule coated with a polymer that is photopolymerizable. Kaetsu does not disclose, teach or suggest a substrate or drug delivery system comprising bioactive molecules that are protected during a photopolymerization process by a material insoluble to surrounding monomers, and monomers that are exposed to the photopolymerization. Applicant therefore respectfully submits that Kaetsu does not disclose, teach or suggest the claims of the present invention, and requests reconsideration and withdrawal of the pending rejections.

#### **Claim Rejections under 35 U.S.C. § 103**

Claims 1, 3, 6, 12, 21, 25-33, 39, 48, and 52-59 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kaetsu in view of Sasaki. Claims 22, 23, 49 and 50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kaetsu and Sasaki, and in further view of U.S. Patent No. 5,213,808 to Bar-Shalom et al. (hereinafter "Bar-Shalom").

Applicant incorporates its discussion of Kaetsu above. Sasaki, which discloses a photopolymerizable composition, does not make up for the shortfalls of Kaetsu. Bar-Shalom, which discloses a controlled release composition with an initial burst of degradation, similarly does not make up for the shortfalls of Kaetsu. Applicant therefore respectfully submits that none of Kaetsu, Sasaki, nor Bar-Shalom, alone or in combination, render the claims obvious.

Based upon the above, Applicant respectfully requests that the Examiner reconsider and withdraw all outstanding rejections and objections. Favorable consideration and allowance are earnestly solicited. Should there be any questions after reviewing this paper, the Examiner is invited to contact the undersigned at 617-248-4054.

Respectfully submitted,

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